IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : TILSTAM, Ulf et al.

Serial No.: 09/471,040 Group Art Unit: 1623

Filed: 12/23/1999 Examiner: OWENS, Jr., Howard V.

For: PROCESS FOR THE PRODUCTION OF FLUDARABINE-PHOSPHATE LITHIUM, SODIUM, POTASSIUM, CALCIUM AND MAGNESIUM SALTS AND PURIFICATION PROCESS FOR THE PRODUCTION OF FLUDARABINE-PHOSPHATE AND FLUDARABINE-PHOSPHATE WITH A PURITY OF AT LEAST 99.5%

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:

- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
- ☐ within three months of the actual filing date of the national phase of a PCT application; OR
- ☒ before the mailing of a first substantive office action (including after filing of an RCE).

☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:

a final rejection under 37 C.F.R. 1.113;
termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

☐ a check covering the fee of $180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

☐ a final action under 37 C.F.R. § 1.113;

☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2);

☐ OR a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of $180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).

☐ Copies of materials listed but not attached were cited in an international search report dated _____.

☒ Not required by 37 CFR § 1.98.

☒ Copies of the materials listed are attached (except for the foregoing).

Non-English Language References

☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone
Y = document of particular relevance when it is combined with another such document
A = document defining the general state of the art
O = non-written disclosure
P = intercalated document
T = document cited to understand the theory or principle underlying the invention
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date
D = cited in the application
L = cited for another reason
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☐ Translation of other relevant information on foreign search report

Payment of Fees Due (If Any):

☐ A check for $_____ covering the fee identified above is attached.

☐ Please charge to Deposit Account No. 13-3402 $_____ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

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Attorney Docket No.: SCH-1615-D01

Date: 1 June 2005

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	09/471,040
Filing Date	12/23/1999
First Named Inventor	TILSTAM, Ulf et al.
Group Art Unit	1623
Examiner Name	OWENS, Jr., Howard V.
Attorney Docket Number	SCH-1615-D01

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
	A1	5,110,919		Blumbergs	05-05-1992
	A2	3,703,507		Haskell, T. H. et al.	11-21-1972

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (*if known*)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	B1	DE	195 43 052	A1	Schering AG	05-07-1997		
	B2	WO	91/08215		Ash Stevens, Inc.	06-13-1991		
	B3	WO	94/12514		Schering AG	06-09-1994		
	B4	WO	97/18211		Archimica S.P.A.	05-22-1997		
	B5	EP	1 047 704	B1	Schering AG	11-30-1998		X

Examiner Signature		Date Considered	

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[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached. Number refers to English language corresponding family member.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

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Group Art Unit	1623
Examiner Name	OWENS, Jr., Howard V.
Attorney Docket Number	SCH-1615-D01

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	C1	Notice of Opposition to European Patent No. 1 047 704, Application No. 98965703.6, Mayne Pharma Pty, Ltd., Date of Mention 01/29/2003.	
	C2	Declaration of Donald Corcoran, dated 10/27/2003.	
	C3	Letter from Alltech Association Australia Pty, Ltd., dated 10/22/2003 with declaration attached from Dr. Phillip J. Anevski, dated 10/23/2003.	
	C4	Letter from Boult Wade Tennant dated 10/29/2003.	
	C5	The Nucleic Acids Chemistry and Biology, Volume 1, 1955, chapter 6, pages 211 - 241.	
	C6	Exhibit C, Fludarabine Phosphate >99.5% Pure After Dowex 1X4 Column, 7/24/2003, with attached, Waldo E. Cohn, The Anion-Exchange Separation of Ribonucleotides, 72 J. Am. Chem. Soc., pp. 1471 - 1478 (1950)	
	C7	Waldo E. Cohn, Methods of Isolation and Characterization of Mono and Polynucleotides by Ion Exchange Chromatography, 107 Methods in Enzymology, pp. 724 - 743 (1967).	
	C8	In the House of Lords, Biogen Inc. v. Medeva PLC, dated October 31, 1996, pages 1 - 54.	
	C9	Henry Herbert Cobb III, Stability of Fludarabine Phosphate, Pentostatin, and Amsacrine in Commonly Used Infusion Solutions and After Filtration, and Osmolality of Various Constituted Chemotherapeutic Agents, pp. 20 - 48 (1995).	
	C10	Boards of Appeal of The European Patent Office, Decision, Previously Presented. 20 - 48, Case No. T 0990/96 - 3.3.1. (02/12/1998)	
	C11	The MERCK Index, Twelfth Edition, 1996,	
	C12	Official Monographs, USP 26, Fludarabine Phosphate, pages 3096 - 3097 (1996).	
	C13	U.S. Schering's Reply	
	C14	Notice of Opposition to European Patent No. EP 1047704, App. No. 98965703.6, by Curtis, Phillip Anthony, 11/11/2003.	
	C15	Notice of Opposition to European Patent No. EP 1047704, App. No 98965703.6, by Sicor, Inc., Date of Mention 1/29/2003.	
	C16	EP-B-1047704 Opposition by SICOR Inc., in European Patent No. 1047704, App. No. 98965703.6, Experimental Report, dated 10/29/2003.	
	C17	PCT Report for App. No. PCT/EP98/07651, dated 1/27/00.	

Examiner Signature		Date Considered	

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